EPA REGISTRATION FILE JACKET

REGISTRATION # 264-846
Volume 2

6

FOR OFFICIAL USE ONLY

FILE SYMBOL
REGISTRATION NO.

CONFIDENTIAL STATEMENT OF FORMULA ENCLOSED

DATE SUBMITTED	SUBMITTED BY (✓)	
	APPLICANT	BASIC SUPPLIER

Do Not Write Comments, Formula, or Parts of Formula on This Envelope

NOTE

It shall be unlawful—for any person to use for his own advantage or to reveal, other than to the Secretary, or officials or employees of the United States Department of Agriculture or other Federal agencies, or to the courts in response to a subpoena, or to physicians, and in emergencies to pharmacists and other qualified persons, for use in the preparation of antidotes, in accordance with such directions as the Secretary may prescribe, any information relative to formulas of products acquired by authority of Section 4 of the "Federal Insecticide, Fungicide, and Rodenticide Act."

PR FORM 9-11
(MARCH 2006)

USDA-ARS

Reg # 264-846

Page _____ is not included in this copy.

Pages 3 through 4 are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

✓ The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

_____ Internal deliberative information.

_____ Attorney-Client work product.

_____ Claimed Confidential by submitter upon submission to the Agency.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

Bayer CropScience

June 11, 2007

Document Processing Desk
Office of Pesticide Programs (7505P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, Virginia 22202-4501

ATTENTION: Kable Bo Davis (Insecticide-Rodenticide Branch, RD)

Re: Final Printed Label for AE 1283742 (EPA Reg. No. 264-846)

Bayer CropScience
2 T.W. Alexander Drive
P. O. Box 12014
Research Triangle Park,
NC 27709
Tel: 919 549-2000

Dear Mr. Davis,

In compliance with your May 30, 2007 approval letter, we are herein submitting one copy of the final printed label for AE 1283742 dated May 30, 2007 for your record. All of the requested revision has been incorporated in this final printed label.

Please let me know at jamin.huang@bayercropscience.com or at 919-549-2634 if you have any questions regarding this submission.

Sincerely,

Jamin Huang
Product Registration Manager

Attachment

5

N REVIEWED
In Accordance with PR Notice 82-2
Based on Draft Labeling Dated
MAY 30 2007

AE 1283742

AE 1283742 is a systemic insecticide seed treatment for use on cotton for the control of certain insect pests.
All seed treated with this product must be conspicuously coloured at the time of treatment.

ACTIVE INGREDIENT:	
Imidacloprid	32.8%
Clothianidin	14.1%
INERT INGREDIENTS:	53.1%
TOTAL	100.0%

Contains 3.5 lb active per gallon (420 grams per liter) imidacloprid and t.5 lb active per gallon (t80 grams per liter) clothianidin

E.P.A. Reg. No. 264-846 **E.P.A. Est. No.**

KEEP OUT OF REACH OF CHILDREN
CAUTION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

For MEDICAL And TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577
For PRODUCT USE Information Call 1-866-99BAYER (1-866-992-2937)

FIRST AID

IF SWALLOWED:	• Immediately call a poison control center or doctor for treatment advice. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Have person sip a glass of water if able to swallow. • Do not give anything by mouth to an unconscious person.
IF IN EYES:	• Hold eye open and rinse slowly and gently with water for t5-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. • Call a poison control center or doctor for treatment advice.
IF INHALED:	• Move person to fresh air. • If person is not breathing, call 91 t or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
For MEDICAL Emergencies Call 24 Hours A Day 1-800-334-7577. Have the product container or label with you when calling a poison control center or doctor or going for treatment.	

NOTE TO PHYSICIAN: No specific antidote is available. Treat the patient symptomatically.

PRECAUTIONARY STATEMENTS

CAUTION
HAZARD TO HUMANS AND DOMESTIC ANIMALS

Harmful if absorbed through skin. Harmful if swallowed. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category C on an EPA chemical resistance category selection chart.

Applicators and other handlers must wear: Long-sleeved shirt and long pants, chemical-resistant gloves (such as nitrile, butyl, neoprene, barrier laminate, polyvinyl chloride or Viton) and shoes plus socks. Follow manufacturer's instructions for cleaning/maintaining PPE. If no instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

6

USER SAFETY RECOMMENDATIONS

Users should: Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove Personal Protective Equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This product is toxic to aquatic invertebrates. Contain any product spills or equipment leaks and dispose of wastes according to disposal instructions on this label. Do not contaminate water when disposing of equipment washwaters.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
Read entire label before using this product.

For use by commercial treaters only. Not for use in agricultural establishments in hopper-box, slurry-box, or similar on farm seed treatment applicators used at planting. This product is to be used in commercial liquid or slurry treaters. Mix thoroughly before use or use entire container at one time.

All seed treated with this product must be conspicuously coloured at the time of treatment. This product contains no colorant. An appropriate colorant must be added when this product is applied to seed to distinguish and prevent subsequent inadvertent use as a food for man or feed for animals. Regulations pertaining to coloration of treated seed enforced by *40 CFR 153.155* must be strictly adhered to when using this product.

STORAGE AND DISPOSAL

STORAGE

Do not contaminate water, food or feed by storage or disposal. Store in a cool, dry secured storage area.

PESTICIDE DISPOSAL

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL

Contact Bayer CropScience or your chemical supplier for container return instructions. If container is not returned in accordance with instructions, triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

STORED SEED PROTECTION:

AE 1283742 will provide protection to seed against injury from the following insects: Indian Meal Moth (*Plodia interpunctella*), Rice Weevil (*Sitophilus oryzea*), Red Flour Beetle (*Tribolium castaneum*), Rusty Grain Beetle (*Cryptolestes ferrugineus*), and Lesser Grain Borer (*Rhizopertha dominica*). It is recommended that seed with existing populations of stored grain pests be fumigated prior to treating and bagging seed.

FOR EARLY SEASON PROTECTION AGAINST CERTAIN SUCKING INSECTS:

AE 1283742 will aid in the protection of seeds and seedlings against injury by certain early season insects.

COTTON (DELINTED SEED ONLY):

Applied at labeled rates, AE 1283742 will provide protection of seedlings against injury by early season thrips, black cutworm and aphids. Where the specific application rate is desired on an individual seed basis, apply at 0.375 - 0.535 mg of total active ingredients per seed. Do not apply more than 18.3 fluid ounces per hundredweight of seed. Each fluid oz of AE 1283742 contains a total of 17.7 g active imidacloprid and clothianidin. Otherwise, apply at 12.8 - 18.3 fluid ounces per hundredweight of seed. Regardless of the type of application (seed treatment, soil or foliar) do not apply more than a total of 0.5 lb. of imidacloprid per acre per cropping cycle.

ROTATIONAL CROPS:

Treated areas may be replanted with any crop specified on both imidacloprid and clothianidin labels, or any crop for which a tolerance exists for both active ingredients, as soon as practical following the last application. Areas planted with treated seed may be replanted immediately with cotton, corn, rapeseed and canola. These areas may also be replanted after 30 days with cereal grains, soybeans, dried beans and dried peas. Do not plant any other crop in the treated area for at least one year after treated seeds are planted.

LABELLING OF TREATED SEED

Seed commercially treated with AE 1283742 must be labeled or tagged as follows:

- This seed has been treated with AE 1283742, which contains imidacloprid and clothianidin.
- Do not use treated seed for food, feed or oil processing.
- Store away from feeds and foodstuffs.
- Wear long-sleeved shirt, long pants and waterproof gloves when handling treated seed.

- Dispose of all excess treated seed. Left over treated seed may be double sown around the headland or buried away from water sources in accordance with local requirements. Do not contaminate water bodies when disposing of planting equipment washwaters.
- Dispose of seed packaging in accordance with local requirements.
- This compound is toxic to birds and mammals. Treated seeds exposed on soil surface may be hazardous to birds and mammals. Cover or collect treated seeds spilled during loading.
- Treated areas may be replanted with any crop specified on both imidacloprid and clothianidin labels, or any crop for which a tolerance exists for both active ingredients, as soon as practical following the last application. Areas planted with treated seed may be replanted immediately with cotton, corn, rapeseed and canola. These areas may also be replanted after 30 days with cereal grains, soybeans, dried beans dried peas. Do not plant any other crop in the treated area for at least one year after treated seeds are planted.

All seed treated with this product must be conspicuously colored at the time of treatment. This product contains no colorant. An appropriate colorant must be added when this product is applied to seed to distinguish and prevent subsequent inadvertent use as a food for man or feed for animals. Regulations pertaining to coloration of treated seed enforced by 40 CFR 153.155 must be strictly adhered to when using this product.

IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, disclaimer of Warranties and Limitations of Liability.

Treatment of highly mechanically damaged seed, or seed of known low vigor and poor quality, may result in reduced germination and/or reduction of seed and seedling vigor. Treat and conduct germination tests on a small portion of seed before committing the total seed lot to a selected chemical treatment. Due to seed quality conditions beyond the control of Bayer CropScience, no claims are made to guarantee germination of carry-over seed.

CONDITIONS: The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer CropScience. All such risks shall be assumed by the user or buyer.

DISCLAIMER OF WARRANTIES: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE'S ELECTION, THE REPLACEMNT OF PRODUCT.

NOTICE TO BUYER

Purchase of this material does not confer any rights under patents governing this product or the use thereof in countries outside of the United States.

NET CONTENTS:

Bayer CropScience

Bayer CropScience LP
P.O. Box 12014, 2 T.W. Alexander Drive
Research Triangle Park, North Carolina 27709
1-866-99BAYER (1-866-992-2937)
http://www.bayercropscienceus.com

AE 1283742 (MASTER) EPA Approved 05/30/07.

Certification with Respect to Label Integrity

version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

PROPOSED LABEL		
EPA Registration #	Date Submitted to EPA	Electronic file name
264-846	06/06/07	000264-00846.20070606.**AE**1283742.pdf

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

Signature

06/06/2007
Date

Anna B. Wilkins
Name (typed)

Label Development Specialist
Title

Material to be added to a Mini-Jacket
(in the case where an e-Jacket exists)

Reg. No. 264-846

Send to SIG: check box [4]

This material is:

- € New stamped-accepted label
- € New CSF
- € Notification
- € Final Printed Label
- € Other: New Registration

Instructions: Attach this notice on top of the material. It must be clipped all together and ~~there should be NO STAPLES in the material.~~ Then give the material with this coversheet to staff in the Information Services Center (Room 230).

Reviewer's Name: [signature]

Phone: 306-0415 Division: RD

Date: 5-30-07

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505C)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
_X_ Registration
___ Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
264-846	MAY 30 2007

Term of Issuance:
Conditional

Name of Pesticide Product:
AE 1283742

Name and Address of Registrant (include ZIP Code):
Bayer CropScience
2 T.W. Alexander Drive
Research Triangle Park, NC 27709

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product when the Agency requires all registrants of similar products to submit such data.

2. Make the following label changes before you release the product for shipment:
   a. Revise the EPA Registration Number to read, "*EPA Reg. No. 264-846*".

   b. Revise the **HAZARDS TO HUMANS AND DOMESTIC ANIMALS** section of the label to read "*Harmful if absorbed through skin. Harmful if swallowed. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.*

Signature of Approving Official:

Kable Bo Davis, Entomologist
Insecticide-Rodenticide Branch, Registration Division (7505P)

Date: MAY 30 2007

EPA Form 8570-6

c. Within the **CONDITIONS** section of the label, revise the sentence "*The directions for use of this product are believed to be adequate and should...*" to read "*The directions for use of this product are believed to be adequate and must...*".

d. Within the **DISCLAIMER OF WARRANTIES** section of the label, revise the sentence "*BAYER CROPSCIENCE MAKES NO OTHER WARRANTIES...*" to read "*TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE MAKES NO OTHER WARRANTIES...*".

e. Revise the statements "*Treated seeds exposed on soil surface may be hazardous to birds and other wildlife. Cover or collect treated seeds spilled during loading.*" to read "*This compound is toxic to birds and mammals. Treated seeds exposed on soil surface may be hazardous to birds and mammals. Cover or collect treated seeds spilled during loading.*"

3. The data requirements for storage stability (830-6317) and corrosion characteristics (830- 6320) have not been satisfied, and must be submitted within eighteen months of the date of this letter.

4. Submit one copy of the revised final printed label for the record before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Kable Bo Davis
Entomologist
Insecticide-Rodenticide Branch
Registration Division (7505P)

Enclosure

12

ACCEPTED
with COMMENTS
In EPA Letter Dated:
MAY 30 2007

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 264-846

AE 1283742

AE 1283742 is a systemic insecticide seed treatment for use on cotton for the control of certain insect pests.

All seed treated with this product must be conspicuously coloured at the time of treatment.

ACTIVE INGREDIENT:	
Imidacloprid	32.8%
Clothianidin	14.1%
INERT INGREDIENTS:	53.1%
TOTAL	100.0%

Contains 3.5 lb active per gallon (420 grams per liter) imidacloprid and 1.5 lb active per gallon (180 grams per liter) clothianidin

E.P.A. Reg. No. 264-XXX **E.P.A. Est. No.**

KEEP OUT OF REACH OF CHILDREN

CAUTION

Si usted no entiende le etiqueta, busque a alguien para que se la explique e usted en detalle.
(If you do not understand the label, find someone to explain it to you in detail.)

For MEDICAL And TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577.
For PRODUCT USE Information Call 1-866-99BAYER (1-866-992-2937)

FIRST AID

IF SWALLOWED:	• Immediately call a poison control center or doctor for treatment advice. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Have person sip a glass of water if able to swallow. • Do not give anything by mouth to an unconscious person.
IF IN EYES:	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. • Call a poison control center or doctor for treatment advice.
IF INHALED:	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
IF ON SKIN OR CLOTHING:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.

For MEDICAL Emergencies Call 24 Hours A Day 1-800-334-7577.

Have the product container or label with you when calling a poison control center or doctor or going for treatment.

NOTE TO PHYSICIAN: No specific antidote is available. Treat the patient symptomatically.

PRECAUTIONARY STATEMENTS

CAUTION
HAZARD TO HUMANS AND DOMESTIC ANIMALS

Harmful if swallowed or absorbed through the skin. Avoid contact with skin or clothing. Wash hands thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category C on an EPA chemical resistance category selection chart.

Applicators and other handlers must wear: Long-sleeved shirt and long pants, chemical-resistant gloves (such as nitrile, butyl, neoprene, barrier laminate, polyvinyl chloride or Viton) and shoes plus socks. Follow manufacturer's instructions for cleaning/maintaining PPE. If no instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users should: Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. Remove Personal Protective Equipment immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This product is toxic to aquatic invertebrates. Contain any product spills or equipment leaks and dispose of wastes according to disposal instructions on this label. Do not contaminate water when disposing of equipment washwaters.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
Read entire label before using this product.

For use by commercial treaters only. Not for use in agricultural establishments in hopper-box, slurry-box, or similar on farm seed treatment applicators used at planting. This product is to be used in commercial liquid or slurry treaters. Mix thoroughly before use or use entire container at one time.

All seed treated with this product must be conspicuously coloured at the time of treatment. This product contains no colorant. An appropriate colorant must be added when this product is applied to seed to distinguish and prevent subsequent inadvertent use as a food for man or feed for animals. Regulations pertaining to coloration of treated seed enforced by *40 CFR 153.155* must be strictly adhered to when using this product.

STORAGE AND DISPOSAL

STORAGE

Do not contaminate water, food or feed by storage or disposal. Store in a cool, dry secured storage area.

PESTICIDE DISPOSAL

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL

Contact Bayer CropScience or your chemical supplier for container return instructions. If container is not returned in accordance with instructions, triple rinse (or equivalent). Then offer for recycling or reconditioning or puncture and dispose of in a sanitary landfill or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

STORED SEED PROTECTION:

AE 1283742 will provide protection to seed against injury from the following insects: Indian Meal Moth (*Plodia interpunctella*), Rice Weevil (*Sitophilus oryzea*), Red Flour Beetle (*Tribolium castaneum*), Rusty Grain Beetle (*Cryptolestes ferrugineus*), and Lesser Grain Borer (*Rhizopertha dominica*). It is recommended that seed with existing populations of stored grain pests be fumigated prior to treating and bagging seed.

FOR EARLY SEASON PROTECTION AGAINST CERTAIN SUCKING INSECTS:

AE 1283742 will aid in the protection of seeds and seedlings against injury by certain early season insects.

COTTON (DELINTED SEED ONLY):

Applied at labeled rates, AE f283742 will provide protection of seedlings against injury by early season thrips, black cutworm and aphids. Where the specific application rate is desired on an individual seed basis, apply at 0.375 - 0.535 mg of total active ingredients per seed. Do not apply more than 18.3 fluid ounces per hundredweight of seed. Each fluid oz of AE 1283742 contains a total of 17.7 g active imidacloprid and clothianidin. Otherwise, epply at 12.8 - 18.3 fluid ounces per hundredweight of seed. Regardless of the type of application (seed treatment, soil or foliar) do not apply more than a total of 0.5 lb. of imidacloprid per acre per cropping cycle.

ROTATIONAL CROPS:

Treated areas may be replanted with any crop specified on both imidacloprid and clothianidin labels, or any crop for which a tolerance exists for both active ingredients, as soon as practical following the last application. Areas planted with treated seed may be replanted immediately with cotton, corn, rapeseed and canola. These areas may also be replanted after 30 days with cereal grains, soybeans, dried beans and dried peas. Do not plant any other crop in the treated area for at least one year after treated seeds are planted.

LABELLING OF TREATED SEED

Seed commercially treated with AE 1283742 must be labeled or tagged as follows:

- This seed has been treated with AE 1283742, which contains imidacloprid and clothianidin.
- Do not use treated seed for food, feed or oil processing.
- Store away from feeds and foodstuffs.
- Wear long-sleeved shirt, long pants and waterproof gloves when handling treated seed.

- Dispose of all excess treated seed. Left over treated seed may be double sown around the headland or buried away from water sources in accordance with local requirements. Do not contaminate water bodies when disposing of planting equipment washwaters.
- Dispose of seed packaging in accordance with local requirements.
- Treated seeds exposed on soil surface may be hazerdous to birds end other wildlife. Cover or collect treated seeds spilled during loading.
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IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties end Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

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DISCLAIMER OF WARRANTIES: BAYER CROPSCIENCE MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience Is authorized to make any warranties beyond those contained herein or lo modify the warranties contained herein. BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

LIMITATIONS OF LIABILITY: THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE'S ELECTION, THE REPLACEMNT OF PRODUCT.

NOTICE TO BUYER

Purchase of this material does not confer eny rights under patents governing this product or tha use thereof in countries outside of the United States.

NET CONTENTS:

Bayer CropScience

Bayer CropScience LP
P.O. Box 12014, 2 T.W. Alexander Drive
Research Triangle Park, North Carolina 27709
1-866-99BAYER (1-866-992-2937)
http://www.bayercropscienceus.com

AE 1283742 (PENDING) Submitted 02/18/05.

FEE

DATE OUT: 28 Feb 2007

SUBJECT: **PRODUCT CHEMISTRY REVIEW** **MP [ ] EP [x]**
DP BARCODE No.: D3t4538
Reg. File Symbol No.: 264-IUA
PRODUCT NAME: AE 1283742
COMPANY: Bayer CropScience LP
Decision No.: 354563 **PC CODE:** 044309,t29099
FOOD USE: [x] **Integrated Formulation [ ]**

FROM: Bruce F. Kitchens, Chemist
Technical Review Branch
Registration Division (7505P)

Bruce F. Kitchens
28 Feb 2007
SRm 03-01-07

TO: RM #01, Daniel Kenny/Carmen Rodia
Insecticide-Rodenticide Branch (7505P)
Registration Division (7505P)

INTRODUCTION:

The registrant, Bayer CropScience LP, is submitting an application to register the proposed end-use product, AE 1283742. This submission is part of a tolerance petition for the active ingredient, Clothianidin. The active ingredients in this product are Clothianidin and Imidacloprid at label nominal concentrations of 14.t and 32.8% a.i., respectively. This product is intended for use as an insecticide seed treatment for use on cotton. In support of this request, the registrant has submitted a basic Confidential Statement of Formula (CSF) dated 07 Jan 2005, a draft label, and product chemistry data contained in MRID#464823-0t. The Technical Review Branch (TRB) has been asked to review this submission.

SUMMARY OF FINDINGS

TRB has reviewed this submission and reports the following findings:

t. This product is produced from a registered source of the active ingredient.

2. All inert ingredients are cleared for use in formulated pesticide products. In addition, all inert ingredients are exempt from the requirement of a food tolerance. Several inert ingredients have certified limits wider than the standard certified limits. A rationale was provided for the wider certified limits.

3. The nominal concentration of the active ingredient listed on the proposed CSF and the draft label are the same.

4. The draft label contains the appropriate storage and disposal statements.

5. The active ingredient's certified limits as proposed on the basic CSF are acceptable.

CONCLUSIONS:

TRB has reviewed this submission and concludes the following:

1. The basic formula CSF for the proposed end-use product, AE 1283742 dated 07 Jan 2005 is acceptable.

2. This submission satisfies the data requirements as specified in 40 CFR 158.155, 158.160, 158.165, 158.167, 158.175, and 158.t80 with respect to product identity and composition, description of materials used to produce the product, description of formulation process, discussion of formation of impurities, certified limits, and enforcement analytical method.

3. Except for storage stability/corrosion characteristics studies, the remaining product chemistry Group B data (MRID# 464823-01) adequately fulfill the data requirements. The registrant states that storage stability and corrosion characteristics studies are in progress and will be submitted upon completion.

PRODUCT CHEMISTRY DATA (SERIES 830 Subgroup A)

Subgroup A – Product Identity and Composition	Data Required Fulfilled	MRID No.
830.1550. Chemical Identity	Y	464823-01
830.1600. Beginning Materials	Y	464823-01
830.1650. Formulation Process	Y	464823-01
830.t670. Discussion of Impurities	Y	464823-01
830.t700. Preliminary Analysis	NA	
830.t750. Certified Limits	Y	464823-01
830.t800. Enforcement Analytical Method	Y	464823-0t

17

Enforcement Analytical Method: (MRID No. 464823-01)

The active ingredients, Clothianidin and Imidacloprid, are determined by High Performance Liquid Chromatography (HPLC) using ultraviolet (UV) detection and propiophenone as an internal standard. Method was validated for linearity, precision, and accuracy.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND
TOXIC SUBSTANCES

29/MAR/2005

MEMORANDUM

Subject:	Name of Pesticide Product:	AE 1283742
	EPA Reg. No. /File Symbol:	264-IUA
	DP Barcode:	D314537
	Decision No:	354563
	PC Codes:	129099, 044309
From:	Eugenia McAndrew, Biologist	EM
	Technical Review Branch	
	Registration Division (7505C)	
To:	Carmen Rodia, RM Team 01	
	Insecticide-Rodenticide Branch	
	Registration Division (7505C)	
Applicant:	Bayer CropScience	
	2 T.W. Alexander Drive	
	Research Triangle Park, NC 27709	

FORMULATION FROM LABEL:

	Active Ingredient(s):	% by wt.
129099	Imidacloprid	32.8
044309	Clothianidin	14.1
	Other Ingredients:	53.1
	Total:	100.0

ACTION REQUESTED: "Attached are some acute toxicity data to support the registration of this product."

BACKGROUND: Bayer CropScience has submitted a six pack of acute toxicity studies to support the registration of AE 1283742, EPA File Symbol 264-IUA. The studies were conducted at Bayer Healthcare AG, Wuppertal, Germany with assigned MRID numbers 464324-02 to -07.

RECOMMENDATIONS: The six studies have been reviewed and are classified as acceptable.

The acute toxicity profile for of AE 1283742, EPA File Symbol 264-IUA, is as follows:

acute oral toxicity	III	Acceptable	MRID 46482302
acute dermal toxicity	III	Acceptable	MRID 46482303
acute inhalation toxicity	IV	Acceptable	MRID 46482304
primary eye irritation	IV	Acceptable	MRID 46482305
primary skin irritation	IV	Acceptable	MRID 46482306
dermal sensitization	Negative	Acceptable	MRID 46482307

LABELING: Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System.

PRODUCT ID #: 000264-00846

PRODUCT NAME: AE 1283742

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals:

SIGNAL WORD: CAUTION

Harmful if absorbed through skin. Harmful if swallowed. Avoid contact with skin, eyes or clothing.Wear long-sleeved shirt and long pants, socks, shoes, and chemical-resistant gloves (such as Natural Rubber, Selection Category A).

First Aid:

If on skin:
-Take off contaminated clothing.
-Rinse skin immediately with plenty of water for 15-20 minutes.
-Call a poison control center or doctor for treatment advice.

If swallowed:
-Call a poison control center or doctor immediately for treatment advice.
-Have person sip a glass of water if able to swallow.
-Do not induce vomiting unless told to by a poison control center or doctor.
-Do not give anything to an unconscious person.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

20

User Safety Recommendations:

Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

Reviewer: Eugenia McAndrew March 29, 2005
Risk Manager: 01

STUDY TYPE: Acute Oral Toxicity - S-D Rat; OPPTS 870.1100; OECD 423

TEST MATERIAL: Clothianidin + Imidacloprid 600 (Batch No. 04RCC004P141; 14.58% clothianidin and 32.57% imidacloprid; beige suspension)

CITATION: Schungel, M. Clothianidin + Imidacloprid Combo 600 FS (Cotton ST). Acute toxicity in the rat after oral administration. Bayer Healthcare AG, Wuppertal, Germany. Laboratory Report Number AT01803. January 6, 2005. MRID 46482302. Unpublished.

SPONSOR: Bayer CropScience AG, Alfred-Nobel Str. 50, 40789 Monheim, Germany

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID 46482302), twelve female Wistar HsdCpb:Wu rats (Age: 10-14 weeks; Source: Harlan/Winkelmann GmbH, Borchen, Germany; 160-190 g) were given a single oral dose of Clothianidin + Imidacloprid 600 (Batch No. 04RCC004P141; 14.58% clothianidin and 32.57% imidacloprid; beige suspension). The test substance was formulated in tap water. A fixed dose of 2000 mg/kg of the test substance was administered to the first group of three female rats by oral gavage. Due to the mortality of all three animals, a second group of three female rats were tested at a dose of 300 mg/kg according to the rules of the acute toxic class method. No mortality occurred and another group of three females was tested at 300 mg/kg. Again, no mortality occurred and an additional group of three females was tested at a dose of 500 mg/kg to clarify the result for EPA requirements. Animals were then observed for 14 days.

Oral LD_{50} Females > 500 and < 2000 mg/kg bw

The three animals dosed at 2000 mg/kg died within four hours after test substance administration. Toxic signs noted prior to death included decreased motility, tremor, narrowed palpebral fissure, abdominal position, labored breathing and lateral position. All animals dosed at 300 and 500 mg/kg survived and gained weight with no clinical signs observed. No pathological findings were observed in the animals that died during the observation period or in animals sacrificed at the end of the study period.

Toxicity based on the lack of deaths at the limit dose of 500 mg/kg. EPA Toxicity Category III.

This acute oral study is classified as acceptable. It does satisfy the guideline requirement for an acute oral study (OPPTS 870.1100; OECD 423) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Individual animals were dosed as follows:

Dosage (mg/kg bw)	Number of Deaths/Number Tested		
	Males	Females	Combined
2000	--	3/3	--
300 1st group	--	0/3	--
300 2nd group	--	0/3	--
500	--	0/3	--

Statistics - The LD_{50} value was estimated according to OECD Guideline for Testing of Chemicals No. 423 - "Acute Oral Toxicity - Acute Toxic Class Method" adopted December 17, 2001.

A. **Mortality** - The three animals dosed at 2000 mg/kg died within four hours after test substance administration.

B. Clinical observations - No clinical signs were observed in animals dosed at 300 and 500 mg/kg. The following clinical signs were observed in animals treated with 2000 mg/kg: decreased motility, tremor, narrowed palpebral fissure, abdominal position, labored breathing and lateral position. All surviving animals gained weight.

C. Gross Necropsy - No pathological findings were observed in the animals that died during the observation period or in animals sacrificed at the end of the study period.

D. Reviewer's Conclusions: We agree with the study author's conclusion that the oral LD_{50} for female rats is greater than 500 mg/kg and less than 2000 mg/kg.

Reviewer: Eugenia McAndrew March 29, 2005
Risk Manager: 01

STUDY TYPE: Acute Dermal Toxicity - S-D Rat; OPPTS 870.1200; OECD 402

TEST MATERIAL: Clothianidin + Imidacloprid 600 (Batch No. 04RCC004P141; 14.58% clothianidin and 32.57% imidacloprid; beige suspension)

CITATION: Schungel, M. Clothianidin + Imidacloprid Combo 600 FS (Cotton ST). Acute toxicity in the rat after dermal administration. Bayer Healthcare AG, Wuppertal, Germany. Laboratory Report Number AT01804. January 6, 2005. MRID 46482303. Unpublished.

SPONSOR: Bayer CropScience AG, Alfred-Nobel Str. 50, 40789 Monheim, Germany

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID 46482303), 5/sex of HsdCpb:Wu Wistar rats (Age: 9-13 weeks; Source: Harlan/Winkelmann GmbH, Borchen, Germany; 233-247 g males and 214-226 g females) were dermally exposed to Clothianidin + Imidacloprid 600 (Batch No. 04RCC004P141; 14.58% clothianidin and 32.57% imidacloprid; beige suspension). Four thousand mg/kg of the test substance was applied to an area of approximately 10% of body surface of each animal. The test sites were covered with a gauze patch. After a 24 hour period, the dressings were removed. Animals were then observed for 14 days.

Dermal LD_{50} Males > 4000 mg/kg bw
Dermal LD_{50} Females > 4000 mg/kg bw
Dermal LD_{50} Combined > 4000 mg/kg bw

All animals survived. No clinical signs were noted. Body weight gain was normal in males. A decrease in body weight was observed on day 8 for two females but all females exceeded initial body weight by the end of the study. Gross necropsy revealed no particular findings.

Toxicity based on lack of deaths at 4000 mg/kg. EPA Toxicity Category III.

This acute dermal study is classified acceptable. It does satisfy the guideline requirement for an acute dermal study (OPPTS 870.1200; OECD 402) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Dosage (mg/kg bw)	Number of Deaths/Number Tested		
	Males	Females	Combined
4000	0/5	0/5	0/10

A. Mortality - None

B. Clinical observations - No clinical signs were noted. Body weight gain was normal in males. A decrease in body weight was observed on day 8 for two females but all females exceeded initial body weight by the end of the study.

C. Gross Necropsy - Gross necropsy revealed no particular findings.

D. Reviewer's Conclusions: We agree with the study author's conclusion that the dermal LD_{50} for male and female rats is greater than 4000 mg/kg.

Reviewer: Eugenia McAndrew March 29, 2005
Risk Manager: 01

STUDY TYPE: Acute Inhalation Toxicity -S-D rat; OPPTS 870.1300; OECD 403

TEST MATERIAL: Clothianidin + Imidacloprid 600 (Batch No. 04RCC004P141; 14.58% clothianidin and 32.57% imidacloprid; beige suspension)

CITATION: Pauluhn, J. Clothianidin + Imidacloprid Combo 600 FS (Cotton ST). Acute Inhalation Toxicity in Rats. Bayer Healthcare AG, Wuppertal, Germany. Laboratory Report Number T4073338. February 9, 2005. MRID 46482304. Unpublished.

SPONSOR: Bayer CropScience AG, Alfred-Nobel Str. 50, 40789 Monheim, Germany

EXECUTIVE SUMMARY: In an acute inhalation toxicity study (MRID 46482304), 5/sex of HsdCpb:WU (SPF)Wistar young adult rats (Source: Harlan/Winkelmann GmbH, Borchen, Germany; 184-193 g males and 180-190 g females) were exposed nose only via the inhalation route to Clothianidin + Imidacloprid 600 (Batch No. 04RCC004P141; 14.58% clothianidin and 32.57% imidacloprid; beige suspension) at a test concentration of 2.692 mg/L for a period of four hours. A control group of ten animals was exposed to conditioned dry air only. Animals were then observed for 14 days.

LC_{50} Males > 2.692 mg/L
LC_{50} Females > 2.692 mg/L
LC_{50} Combined > 2.692 mg/L

All animals survived and gained weight. Clinical signs noted included bradypnea, labored breathing patterns, reduced motility, limp, ungroomed haircoat, piloerection, mydriasis and nose reddened. The animals recovered from these symptoms by day 3. A battery of reflex measurements was made on the first post-exposure day. In comparison to the rats of the control group, none of the rats in the test group exhibited changes in the reflex behavior. No observable findings were noted at necropsy. The actual chamber concentration was 2.692 mg/L. The mass median aerodynamic diameter was estimated to be 2.60µm with a geometric standard deviation of 1.90.

Toxicity based on lack of deaths at 2.692 mg/L. EPA Toxicity Category IV.

This acute inhalation study is classified as acceptable. It does satisfy the guideline requirement for an acute inhalation study (OPPTS 870.1300; OECD 403) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

Nominal Concentration (mg/L)	Actual Concentration (mg/L)	MMAD µm	GSD	Mortality/Number Tested		
				Males	Females	Combine
16.928	2.692	2.60	1.90	0/5	0/5	0/10

Test Atmosphere / Chamber Description:

Chamber Volume:	**3.8 L**
Airflow:	**15 LPM**
Temperature:	**22°C**
Relative Humidity:	**94%**

Statistics - Digital Fortran 77 was used for particle size analysis and LC_{50} calculation.

A. Mortality - None

B. Clinical observations - All animals gained weight. Clinical signs noted included bradypnea, labored breathing patterns, reduced motility, limp, ungroomed haircoat, piloerection, mydriasis and nose reddened. The animals recovered from these symptoms by day 3. A battery of reflex measurements was made on the first post-exposure day. In comparison to the rats of the control group, none of the rats in the test group exhibited changes in the reflex behavior.

C. Gross Necropsy - No observable findings were noted.

D. Reviewer's Conclusions: We agree with the study author's conclusion that the LC_{50} for male and female rats is greater than 2.692 mg/L.

Reviewer: Eugenia McAndrew March 29, 2005
Risk Manager: 01

TEST MATERIAL: Clothianidin + Imidacloprid 600 (Batch No. 04RCC004P141; 14.58% clothianidin and 32.57% imidacloprid; beige suspension)

CITATION: Schungel, M. Clothianidin + Imidacloprid Combo 600 FS (Cotton ST). Acute Eye Irritation on Rabbits. Bayer Healthcare AG, Wuppertal, Germany. Laboratory Report Number AT01779. January 11, 2004. MRID 46482305. Unpublished.

SPONSOR: Bayer CropScience AG, Alfred-Nobel Str. 50, 40789 Monheim, Germany

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID 46482305), 0.1 mL of Clothianidin + Imidacloprid 600 (Batch No. 04RCC004P141; 14.58% clothianidin and 32.57% imidacloprid; beige suspension) was instilled into the conjunctival sac of one eye of three female young adult albino rabbits (Strain: Crl:KBL(NZW)BR; Source: Charles River, 88353 KiBlegg, Germany). The other eye served as the control. Animals were then observed at 1, 24, 48 and 72 hours post-instillation. Irritation was scored by the method of Draize. A fluorescein dye evaluation procedure was used at 24 hours to evaluate the extent of corneal damage or to verify reversal of effects.

No corneal opacity or iritis were observed. Conjunctivitis was noted in one eye at the one hour observation resolving by 24 hours.

In this study, formulation is minimally irritating. EPA Toxicity Category IV.

This study is classified as acceptable. It does satisfy the guideline requirement for a primary eye irritation study (OPPTS 870.2400; OECD 405) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS AND DISCUSSION:

	Number "positive"/number tested			
	Hours			
Observations	1	24	48	72
Corneal Opacity	0/3	0/3	0/3	0/3
Iritis	0/3	0/3	0/3	0/3
Conjunctivae:				
Redness	1/3	0/3	0/3	0/3
Chemosis	0/3	0/3	0/3	0/3

*Score of 2 or more required to be considered "positive."

A. Observations: No corneal opacity or iritis were observed. Conjunctivitis was noted in one eye at the one hour observation resolving by 24 hours.

B. Reviewer's Conclusions: The study author's conclusion is that the test substance is not irritating to the eye. We conclude that the test substance is minimally irritating to the eye.

Reviewer: Eugenia McAndrew March 29, 2005
Risk Manager: 01

STUDY TYPE: Primary Dermal Irritation - NW Rabbit; OPPTS 870.2500; OECD 404

TEST MATERIAL: Clothianidin + Imidacloprid 600 (Batch No. 04RCC004P141; 14.58% clothianidin and 32.57% imidacloprid; beige suspension)

CITATION: Schungel, M. Clothianidin + Imidacloprid Combo 600 FS (Cotton ST). Acute Skin Irritation/Corrosion on Rabbits. Bayer Healthcare AG, Wuppertal, Germany. Laboratory Report Number AT01755. January 11, 2005. MRID 46482306. Unpublished.

SPONSOR: Bayer CropScience AG, Alfred-Nobel Str. 50, 40789 Monheim, Germany

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID 46482306), three young adult female albino rabbits (Strain: Crl:KBL(NZW)BR; Source: Charles River, 88353 KiBlegg, Germany) were dermally exposed to 0.5 mL of Clothianidin + Imidacloprid 600 (Batch No. 04RCC004P141; 14.58% clothianidin and 32.57% imidacloprid; beige suspension). The test substance was applied to one 6 cm^2 dose site on the dorsal area of each animal. Test sites were covered with a gauze patch and wrapped with tape for a period of 4 hours. Animals were then observed at 1, 24, 48 and 72 hours after patch removal. Irritation was scored by the method of Draize.

In this study, formulation is minimally irritating to the skin. EPA Toxicity Category IV.

Primary Dermal Irritation Index (PDII) = 0.8 Very slight erythema was noted at one test site at the one hour observation. All sites were free of irritation by 24 hours.

This study is classified as acceptable. It does satisfy the guideline requirement for a primary dermal irritation study (OPPTS 870.2500; OECD 404) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

RESULTS and DISCUSSION:

A. Observations - Very slight erythema was noted at one test site at the one hour observation. All sites were free of irritation by 24 hours

B. Results - PDII - 0.8

C. Reviewer's Conclusions - The study author's conclusion is that the test substance is not irritating to the skin. Based on the slight irritation observed, we conclude that the test substance is minimally irritating to the skin.

Reviewer: Eugenia McAndrew March 29, 2005
Risk Manager: 01

STUDY TYPE: Dermal Sensitization - Guinea Pig; OPPTS 870.2600; OECD 406

TEST MATERIAL: Clothianidin + Imidacloprid 600 (Batch No. 04RCC004P141; 14.58% clothianidin and 32.57% imidacloprid; beige suspension)

CITATION: Schungel, M. Clothianidin + Imidacloprid Combo 600 FS (Cotton ST)

CITATION: Vohr, H.W. Clothianidin + Imidacloprid Combo 600 FS (Cotton ST). Study for the Skin Sensitization Effect in Guinea Pigs (Buehler Patch Test). Bayer Healthcare AG, Wuppertal, Germany. Laboratory Report Number AT01777. January 12, 2005. MRID 46482307. Unpublished.

SPONSOR: Bayer CropScience AG, Alfred-Nobel Str. 50, 40789 Monheim, Germany

EXECUTIVE SUMMARY: In a dermal sensitization study (MRID 46482307) with Clothianidin + Imidacloprid 600 (Batch No. 04RCC004P141; 14.58% clothianidin and 32.57% imidacloprid; beige suspension), 30 young adult SPF-bred female guinea pigs (Strain: Crl:HA; Source: Charles River, 88353 KiBlegg, Germany; 301-413 g) were tested using the Buehler method. The procedures were validated using alpha-Hexylcinnamaldehyde as the positive control substance.

Three times each week for three weeks, a patch loaded with 0.5 mL of undiluted test substance was applied to the left side of each of 20 test animals for a 6-hour exposure period for a total of nine exposures. A group of 10 control animals was tested with a dry patch applied to the left flank. The treatment areas were visually assessed 30 hours after initiation of exposure. Two weeks after the last induction dose, a patch loaded with 0.5 mL of undiluted test substance (the highest non-irritating concentration) was applied to a naive site on each test animal for a 6-hour challenge exposure. Ten naive control guinea pigs were also treated with the undiluted test substance at challenge. Readings were made 30 and 54 hours after the challenge application.

In this study, the formulation is not a dermal sensitizer.

One control animal exhibited labored breathing, paleness and poor general condition and died by day 7 of the study. No dermal irritation was observed at any of the test animal sites during the induction phase. Following the challenge, no dermal irritation was observed in any of the test or naive control animals. The results of the HCA positive control study were appropriate to validate test procedures.

This study is classified as acceptable. It does satisfy the guideline requirement for a dermal sensitization study (OPPTS 870.2600; OECD 406) in the Guinea pig.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. PROCEDURE

A. Induction - Three times each week for three weeks, a patch loaded with 0.5 mL of undiluted test substance was applied to the left side of each of 20 test animals for a 6-hour exposure period for a total of nine exposures. A group of 10 control animals was tested with a dry patch applied to the left flank. The treatment areas were visually assessed 30 hours after initiation of exposure. The animals rested for two weeks.

B. Challenge - Two weeks after the last induction dose, a patch loaded with 0.5 mL of undiluted test substance (the highest non-irritating concentration) was applied to a naive site on each test animal for a 6-hour challenge exposure. Readings were made 30 and 54 hours after the challenge application.

C. Naive Controls - Ten naive control guinea pigs were also treated with the undiluted test substance at challenge.

II. RESULTS and DISCUSSION:

A. Reactions and duration - One control animal exhibited labored breathing, paleness and poor general condition and died by day 7 of the study. No dermal irritation was observed at any of the test animal sites during the induction phase. Following the challenge, no dermal irritation was observed in any of the test or naive control animals.

B. Positive control - The results of the HCA positive control study were appropriate to validate test procedures.

C. Reviewer's Conclusions: We agree with the study author's conclusion that the test substance is not considered to be a dermal sensitizer.

ACUTE TOX ONE-LINERS

1. DP BARCODE: D314537
2. PC CODES: 129099, 044309
3. CURRENT DATE: 29/MAR/2005
4. TEST MATERIAL: Clothianidin + Imidacloprid 600(Batch No. 04RCC004P141; 14.58% clothianidin and 32.57% imidacloprid; beige suspension

Study/Species/Lab Study # /Date	MRID	Results	Tox. Cat.	Core Grade
Acute oral toxicity/rat Bayer Healthcare AG AT011803/1-6-05	46482302	LD_{50} females > 500 and < 2000 mg/kg	III	A
Acute dermal toxicity/rat Bayer Healthcare AG AT01804/1-6-05	46482303	LD_{50} > 4000 mg/kg (males, females combined)	III	A
Acute inhalation toxicity/rat Bayer Healthcare AG T4073338/2-9-05	46482304	LC_{50} > 2.692 mg/L (males, females combined)	IV	A
Primary eye irritation/rabbit Bayer Healthcare AG AT01779/1-11-05	46482305	Conjunctivitis in 1/3 eyes resolving by 24 hours	IV	A
Primary dermal irritation/rabbit Bayer Healthcare AG AT01755/1-11-05	46482306	PDII = 0.8 Very slight erythema at 1/3 sites. No irritation at 24 hours.	IV	A
Dermal sensitization/guinea pig Bayer Healthcare AG AT01777/1-12-04	46482307	Not a sensitizer	–	A

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, W = Waived